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ATTORNEY'S DOCKET NO: C1039.70058US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Heather L. Davis et al.

Serial No:

10/023,909

Confirmation No.:

8458

Filed:

December 18, 2001

For:

USE OF NUCLEIC ACIDS CONTAINING UNMETHYLATED CPG

DINUCLEOTIDE AS AN ADJUVANT

Examiner:

Jeffrey S. Parkin

Art Unit:

1648

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on February (1), 2004.

Helen C. Lockhart

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Transmitted herewith is/are the following document(s):

- [X] Supplemental Information Disclosure Statement;
- [X] PTO Form 1449 (copies of references cited);
- [X] Check in the amount of \$180.00; and
- [X] Return Receipt Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

A check in the amount of \$180.00 is enclosed. If the fee is insufficient, please charge the balance to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully Submitted,

Helen C. Lockhart; Reg. No. 39,248

Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue Boston, MA 02210-2211

(617) 720-3500

Docket No. C1039.70058US00

Date: February 6, 2004

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Helen C. Lockhart, Ph.D., Reg. No. 39,248

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

· Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

02/11/2004 NROCHA1 00000008 10023909

Serial No.: 10/023,909

Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The applicant would like to bring to the Examiner's attention the following copending applications that may contain subject matter related to this application (copies enclosed):

Art Unit: 1648

Docket Number	Serial Number	Filing Date	Inventor(s)
C1037.70013US00	09/776,479	2/2/01	Bratzler et al.
C1037.70016US00	09/009,634	1/20/98	Hutcherson et al.
C1037.70025US00	10/017,995	12/14/01	Bratzler
C1037.70038US01	10/735,592	12/11/03	Krieg et al.
C1037.70041US00	10/613,749	7/3/03	Krieg
C1037.70042US00	10/613,524	7/3/03	Krieg
C1037.70043US00	10/613,739	7/3/03	Krieg
C1037.70044US00	10/613,716	7/3/03	Krieg
C1037.70045US00	10/613,228	7/3/03	Krieg
C1037.70046US00	10/445,247	6/5/03	Krieg
C1037.70048US00	10/644,052	8/19/03	Krieg et al.
C1037.70049US00	10/643,141	8/18/03	Hutcherson et al.
C1037.70051US00	10/666,733	9/19/03	Bratzler et al.
C1037.70052US00	10/668,050	9/22/03	Bratzler et al.
C1039.70021US01	10/719,493	11/21/03	Krieg et al.
C1039.70048US01	TBD	1/30/04	Krieg et al.
C1039.70057US00	09/965,101	9/26/01	Davis et al.
C1039.70060US00	10/112,653	3/29/02	Krieg et al.
C1039.70061US00	10/161,229	6/3/02	Krieg et al.
C1039.70062US00	10/187,489	7/2/02	Krieg et al.
C1039.70063US00	10/224,523	8/19/02	Krieg et al.
C1039.70065US00	10/272,502	10/15/02	Krieg et al.

Docket Number	Serial	Filing Date	Inventor(s)
	Number		
C1039.70067US00	10/300,247	11/20/02	Davis et al.
C1039.70068US00	10/306,522	11/27/02	Krieg et al.
C1039.70069US00	10/314,578	12/9/02	Krieg et al.
C1039.70070US00	10/382,822	3/6/03	Krieg et al.
C1039.70071US00	10/435,656	5/9/03	Krieg et al
C1039.70072US00	10/434,696	5/9/03	Davis et al.
C1039.70073US00	10/743,625	12/22/03	Krieg et al.
C1039.70075US00	10/613,916	7/3/03	Krieg et al
C1039.70077US00	10/619,279	7/14/03	Krieg
C1039.70078US00	10/627,331	7/25/03	Krieg et al.
C1039.70079US00	10/627,413	7/25/03	Krieg et al.
C1039.70082US00	10/631,676	7/30/03	Krieg et al.
C1039.70083US00	10/690,495	10/21/03	Krieg
C1039.70083US01	TBD	1/30/04	Krieg et al.
C1039.70084US00	10/649,584	8/25/03	Krieg et al.
C1041.70016US00	09/954,987	9/17/01	Bauer et al.
C1041.70019US00	10/140,013	5/6/02	Schetter et al.
C1041.70029US00	10/212,133	8/1/02	Lipford et al.
C1041.70031US00	10/265,072	10/5/02	Lipford
C1041.70035US00	10/373,381	2/24/03	Wagner et al.
C1041.70037US00	10/407,952	4/4/03	Lipford et al.
C1041.70040US00	10/666,844	9/19/03	Lipford et al.

The following are remarks concerning the other information cited:

Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted, Heather L. Davis et al., *Applicant*

Rv

Helen C. Lockhart, Ph.D., Reg. No. 39,248

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Docket No. C1039.70058US00

Date: February \boldsymbol{b} , 2004

XNDDX

FORM PTO-LAM/A and B (Modified)

FORM ATTY. DOCKET NO.: C1039.70058US00

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

Sheet 1 of 3

APPLICATION NO.: 10/023,909 ATTY. DOCKET NO.: C1039.70058US00

FILING DATE: 12/18/2001 CONFIRMATION NO.: 8458

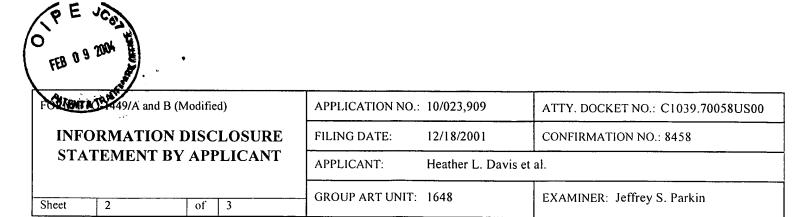
APPLICANT: Heather L. Davis et al.

GROUP ART UNIT: 1648

EXAMINER: Jeffrey S. Parkin

U.S. PATENT DOCUMENTS

Examiner's Cite		U.S. Patent Document		Name of Patentee or Applicant of Cited	Date of Publication or of issue of Cited Document	
Initials	Initials No.	Number	Kind Code	Document	MM-DD-YYYY	
	Al	6,194,388	Bl	Krieg et al.	02-27-2001	
	A2	6,207,646	B1	Krieg et al.	03-27-2001	
	A3	6,214,806	B1	Krieg et al.	04-10-2001	
	A4	6,218,371	Bl	Krieg et al.	04-17-2001	
	A5	6,225,292	Bl	Raz et al.	05-01-2001	
	A6	6,239,116	Bl	Krieg et al.	05-29-2001	
	A7	6,339,068		Krieg et al.	01/15/2002	
	A8	6,406,705	B1	Davis et al.	06-18-2002	
	A9	6,429,199	B1	Krieg et al.	08-06-2002	
	A10	6,498,148	Bl	Raz	12/24/2002	
	All	6,514,948	Bl	Raz, et atl	02/04/2003	
	A12	6,534,062	B2	Krieg, et al.	03/18/2003	
	A13	6,552,006	B2	Raz et al.	04/22/2003	
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	A15	6,589,940	Bl	Raz et al.	07/08/2003	
	A16	6,610,661	B1	Carson et al.	08/26/2003	
	A17	6,653,292	B1	Krieg et al.	11/25/2003	
	A18	US 2001/0046967		Van Nest	11/29/2001	
	A19	US 2002/0028784		Van Nest	03/11/2002	
	A20	US 2002/0042387		Raz et al.	04/11/2002	
	A21	US 2002/0055477	Al	Nest et al	05/09/2002	
	A22	US 2002/0086839		Raz et al.	07/04/2002	
	A23	US 2002/0098199	A1	Van Nest et al.	07/25/2002	
	A24	US 2002/0107212	Al	Van Nest et al.	08/08/2002	
	A25	US 2002/0142978	Al	Raz et al.	10/03/2002	
•	A26	US 2002/0156033	Al	Bratzler et al.	10/24/2002	
	A27	US 2003/0022852		Van Nest et al.	1/30/2003	
	A28	US 2003/0049266	Al	Fearon et al.	03/13/2003	
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	A30	US 2003/0059773		Van Nest et al.	01/30/2003	
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	A32	US 2003/0078223	Al	Raz et al.	04/24/2003	
	A33	US 2003/0092663	Al	Raz	05/15/2003	
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	A36	US 2003/0125284		Raz et al.	07/03/2003	



U.S. PATENT DOCUMENTS

Examiner's	Cite	U.S. Patent Document		Name of Patentee or Applicant of Cited	Date of Publication or of issue	
Initials	No.	Number	Kind Code	Document	of Cited Document MM-DD-YYYY	
	A37	US 2003/0129251	Al	Van Nest et al.	07/10/2003	
	A38	US 2003/0130217		Raz et al.	07/10/2003	
	A39	US 2003/0133988	A1	Fearon et al.	07/17/2003	
	A40	US 2003/0143213	Al	Raz et al.	07/37/2003	
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	A42	US 2003/0175731	A1	Fearon et al.	09/18/2003	
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	A45	US 2003/0199466	A1	Fearon et al.	10/23/2003	
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Examiner's	Cite	For	eign Patent Docur	nent	Name of Patentee or Applicant of Cited	Date of Publication of	Translation
Initials	No.	Office/ Country	Number	Kind Code	Document (not necessary)	Cited Document MM-DD-YYYY	(Y/N)
	B1	wo	99/11275	A2	Regents of the University of CA	03/11/1999	
	B2	WO	99/62923	A2	Dynavax Tech. Corp	12/09/1999	
	В3	WO	00/20039	Al	Regents of the University of CA	04/13/2000	
	B4	wo	00/62787	Al	Regents of the University of CA	10/26/2000	
	B5	WO	98/55609	Al	Regents of the University of CA	10/12/1998	
÷	В6	wo	00/21556	Al	Dynavax Tech. Corp	04/20/2000	
	B7	WO	01/02007	Al	Regents of the University of CA	01/11/2001	
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	B9	WO	01/55341	A2	Regents of the University of CA	08/02/2001	
	B10	WO	01/68077	A2	Dynavax Tech. Corp	09/20/2001	
	B11	WO	01/68078	A2	Dynavax Tech. Corp	09/20/2001	
	B12	WO	01/68103	A2	Dynavax Tech. Corp	09/20/2001	
	B13	WO	01/68116	A2	Dynavax Tech. Corp	09/20/2001	
	B14	WO	01/68117	A2	Dynavax Tech. Corp	09/20/2001	

FEB 0 9 2004 TE			
49/A and B (Modified)	APPLICATION NO.:	10/023,909	ATTY. DOCKET NO.: C1039.70058US00
INFORMATION DISCLOSURE	FILING DATE:	12/18/2001	CONFIRMATION NO.: 8458
STATEMENT BY APPLICANT	APPLICANT:	Heather L. Davis et	al.
Sheet 3 of 3	GROUP ART UNIT:	1648	EXAMINER: Jeffrey S. Parkin

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's	Cite	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item	Translation
Initials	No	(book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s),	(Y/N)
•		publisher, city and/or country where published.	
	C1	Elkins, K. L., Rhinehart-Jones, T. R., et al., "Bacterial DNA containing CpG motifs stimulates	
•		lymphocyte-dependent protection of mice against lethal infection with intracellular bacteria." J	
V		Immunol 162:2291-2298, 1999.	
	C2	Freidag, B. L et al., "CpG oligodeoxynucleotides and interleukin-12 improve the efficacy of	
		Mycobacterium bovis BCG vaccination in mice challenged with M. tuberculosis.: Infect Immun	
		68:2948-2953, 2000.	
	C3	Hayashi, T.et al., "Enhancement of innate immunity against Mycobacterium avium infection by	
		immunostimulatory DNA is mediated by indoleamine 2,3-dioxygenase." Infect Immun 69:6156-	
		6164, 2001.	
	C4	Juffermans, N. P. et al., "CpG oligodeoxynucleotides enhance host defense during murine	
		tuberculosis." Infect Immun 70:147-152, 2002.	
	C5	Klinman, D. M. et al., "Repeated administration of synthetic oligodeoxynucleotides expressing CpG	
		motifs provides long-term protection against bacterial infection. Infect Immun 67:5658-5663, 1999"	
	C6	Klinman, D. M., et al. Activation of the innate immune system by CpG oligodeoxynucleotides:	
		immunoprotective activity and safety. Springer Semin Immunopathol 22:173-183, 2000	
	C7	Krieg, A. M., et al., "CpG motifs in bacterial DNA and their immune effect." Annu Rev Immunol	
		20:709-760, 2002.	
	C8	Lipford, G. B. et al. "Immunostimulatory DNA: sequence-dependent production of potentially	
		harmful or useful cytokines." Eur J Immunol 27:3420-3426, 1997.	
	C9	Sedegah, M.et al. "Interleukin 12 induction of interferon g-dependent protection against malaria."	
İ		Proc Natl Acad Sci U S A 91:10700-10702, 1994.	[
	C10	Sethi, S. et al. "Postexposure prophylaxis against prion disease with a stimulator of innate	
		immunity." Lancet 360:229-230, 2002.	
	C11	Stacey, K. J et al. "Immunostimulatory DNA as an adjuvant in vaccination against Leishmania	
1		major." Infect Immun 67:3719-3726, 1999	
	C12	Walker, P. S. et al. "Immunostimulatory oligodeoxynucleotides promote protective immunity and	
		provide systemic therapy for leishmaniasis via IL-12- and IFN-g-dependent mechanisms." <i>Proc Natl</i>	
1		Acad Sci U S A 96:6970-6975, 1999.	
	C13	Zimmermann, S. et al., "CpG oligodeoxynucleotides trigger protective and curative Th1 responses in	
		lethal murine leishmaniasis." J Immunol 160:3627-3630, 1998.	

EXAMINER	DATE CONSIDERED

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[NOTE - Must provide a copy of any patent, publication, other information listed, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]